UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

## NOTICE OF ALLOWANCE AND FEE(S) DUE

22428

7590

10/30/2008

FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007 EXAMINER
PROUTY, REBECCA E

ART UNIT
PAPER NUMBER

1652

DATE MAILED: 10/30/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,954	05/24/2002	Eric Samain	065691-0267	6242

TITLE OF INVENTION: METHOD FOR PRODUCING OLIGOPOLYSACCHARIDES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$0	\$0	\$1510	01/30/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

### Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

(571)-273-2885 or <u>Fax</u>

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for

maintenance fee notifications. Note: A certificate of mailing can only be used for domestic mailings of the CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. 22428 7590 10/30/2008 Certificate of Mailing or Transmission FOLEY AND LARDNER LLP I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. **SUITE 500** 3000 K STREET NW WASHINGTON, DC 20007 (Depositor's name (Signature (Date APPLICATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE 10/019.954 05/24/2002 Eric Samain 065691-0267 6242 TITLE OF INVENTION: METHOD FOR PRODUCING OLIGOPOLYSACCHARIDES APPLN. TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional NO \$1510 \$0 \$0 \$1510 01/30/2009 **EXAMINER** ART UNIT CLASS-SUBCLASS PROUTY, REBECCA E 1652 435-084000 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. or agents OR, alternatively, (2) the name of a single firm (having as a member a ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) 4a. The following fee(s) are submitted: lssue Fee A check is enclosed. Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_\_ (enclose an extra copy of this fo Advance Order - # of Copies \_ (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ■ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. Authorized Signature Date Typed or printed name Registration No. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



# United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,954	05/24/2002	Eric Samain	065691-0267	6242
22428 7	590 10/30/2008		EXAMINER	
FOLEY AND LARDNER LLP			PROUTY, REBECCA E	
SUITE 500			ART UNIT	PAPER NUMBER
3000 K STREET NW WASHINGTON, DC 20007			1652 DATE MAILED: 10/30/200	8

## **Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 57 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 57 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 (571)-272-4200.

	Application No.	Applicant(s)		
	10/019,954	SAMAIN ET AL.		
Notice of Allowability	Examiner	Art Unit		
	Rebecca E. Prouty	1652		
The MAILING DATE of this communication app All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85 NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.31:	S (OR REMAINS) CLOSED in ) or other appropriate commu RIGHTS. This application is s	this application. If not included nication will be mailed in due cours		
1. 🔀 This communication is responsive to the amendment of 7/2	<u>/11/08</u> .			
2. X The allowed claim(s) is/are <u>1,5-7,9-12,27-30,39 and 48.</u>				
<ul> <li>3.</li></ul>		or (f).		
2. Certified copies of the priority documents have		n No		
Copies of the certified copies of the priority do			om the	
International Bureau (PCT Rule 17.2(a)).	Journality Have Book 1000ivoc	in the national stage application in		
* Certified copies not received:				
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDON! THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		a reply complying with the requiren	nents	
4. A SUBSTITUTE OATH OR DECLARATION must be subn INFORMAL PATENT APPLICATION (PTO-152) which give			E OF	
5. CORRECTED DRAWINGS ( as "replacement sheets") mu	st be submitted.			
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached				
1) ☐ hereto or 2) ☐ to Paper No./Mail Date	_,			
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date				
Identifying indicia such as the application number (see 37 CFR each sheet. Replacement sheet(s) should be labeled as such in			) of	
6. DEPOSIT OF and/or INFORMATION about the deposit attached Examiner's comment regarding REQUIREMENT			he	
Attachment(s)	_			
1. Notice of References Cited (PTO-892)		ormal Patent Application		
2. Notice of Draftperson's Patent Drawing Review (PTO-948)		ımmary (PTO-413), Mail Date		
3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date	7. 🛛 Examiner's	Amendment/Comment		
4. Examiner's Comment Regarding Requirement for Deposit	8. 🛛 Examiner's	Statement of Reasons for Allowanc	е	
of Biological Material	9.	·		
Rebecca E. Prouty				
Primary Examiner Art Unit: 1652				

Application/Control Number: 10/019,954

Art Unit: 1652

Claims 2-4, 8, 13, 14, 18-20, 25, and 26 have been canceled. Claims 1, 5-7, 9-12, 15-17, 21-24, and 27-48 and are still at issue and are present for examination.

Claims 15-17, 21-24, 29, 31-38, and 40-46 stood previously withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim.

However, Claim 1 is now allowable. The restriction

requirement with regard to the species of glycosyltransferases and some of the species of oligosaccharide (i.e., those which comprise lactose), as set forth in the Office action mailed on 10/1/04, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim. Claim 29, directed to methods of producing  $\beta$ -D-GlcNac-[1 $\rightarrow$ 3]- $\beta$ -D-Gal- $[1\rightarrow 4]$ -D-Glc using the enzyme  $\beta$ -1,3-N-acetyl-galactosaminyltransferase is no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim. However, claims 15-17, 21-24, 1-38, and 40-46, directed to use of precursors withdrawn from consideration will not be rejoined because they do not require all the limitations of an allowable claim. Allowed claim 1 is restricted to the elected species of

Application/Control Number: 10/019,954 Page 3

Art Unit: 1652

exogenous precursor being lactose and no claims generic with respect to the exogenous precursor are allowed.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Rouget Henschel on 10/2/08.

## EXAMINER'S AMENDMENT

Art Unit: 1652

In order to place the case in compliance with 37 CFR 1.52(b)(4), replace the abstract with the abstract provided on a separate sheet attached hereto.

In Claim 7, lines 2-8 and Claim 48, lines 11-17 replace  $--\beta-1,3-N$ -acetyl-glucosaminyl-transferase,  $\beta-1,3$ -galactosyl-transferase,  $\beta-1,3-N$ -acetyl-galactosaminyl-transferase,  $\beta-1,3-N$ -glucuronosyl-transferase,  $\beta-1,3-N$ -acetyl-galactosaminyl-transferase,  $\beta-1,4-N$ -acetyl-galactosaminyl-transferase,  $\beta-1,4-N$ -galactosyl-transferase,  $\alpha-1,3$ -galactosyl-transferase,  $\alpha-1,4-$ galactosyl-transferase,  $\alpha-2,3$ -sialyl-transferase,  $\alpha-2,6$ -sialyl-transferase,  $\alpha-2,8$ -sialyl-transferase,  $\alpha-1,2$ -fucosyl-transferase,  $\alpha-1,3$ -fucosyl-transferase and  $\alpha-1,4$ -fucosyl-transferase,  $\alpha-1,4$ -galactosyl-transferase,  $\alpha-1,3$ -galactosyl-transferase,  $\alpha-1,4$ -galactosyl-transferase,  $\alpha-1,3$ -galactosyl-transferase and  $\alpha-1,3$ -fucosyl-transferase.--

In Claim 29, line 3, insert --further comprising the addition of an inducer to said culture medium to induce the expression in said cell of said enzyme and/or of a protein involved in said transport, -- before --wherein:--.

In Claim 30, replace --transport-wherein:-- with
--transport, wherein:--.

Cancel Claims 15-17, 21-24, 31-38, and 40-47.

Application/Control Number: 10/019,954

Art Unit: 1652

The following is an examiner's statement of reasons for allowance:

Page 5

Applicants have submitted evidence that the publication date of the Bettler et al. is actually September 24, 1999 and have a submitted a translation of their foreign priority document which provides support for all of the instantly allowed claims. As such Bettler et al. is not prior art to these claims. Absent the teachings of Bettler et al. regarding the advantages of producing oligosaccharides in vivo within an actively growing cell, the previous rejection of the claims is withdrawn as the prior art taught production of oligosaccharides either in vitro using added purified enzyme and substrates, or using cells secreting the enzyme (see for example Herrmann et al.) or using permeabilized cells (Kozumi et al.) or cell lysates (see for example Prieto et al.).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Application/Control Number: 10/019,954

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/ Primary Examiner Art Unit 1652 Page 6

Application/Control Number: 10/019,954 Page 7

Art Unit: 1652

#### Abstract

The invention concerns the production by microbiological process of oligopolysaccharides of biological interest. More particularly, the invention concerns a method for synthesizing in vivo oligopolysaccharides by internalization of an exogenous precursor in growing bacterial cells expressing adequate modifying and glycosylating genes.